

K122074

## 510(k) SUMMARY

OCT 12 2012

### iFuse Implant System®

#### 510(k) Owner's Name, Address, and Telephone Number

SI-BONE, Inc.  
3055 Olin Avenue, Suite 2200  
San Jose, CA 95128  
(408) 207-0700

#### Contact Person

Cindy Domecus, R.A.C. (US & EU)  
Principal, Domecus Consulting Services LLC  
Regulatory Consultant to SI-BONE, Inc.  
Email: [domecusconsulting@comcast.net](mailto:domecusconsulting@comcast.net)  
Phone: 650-343-4813  
Mobile: 650-773-3445  
Facsimile: 650-343-7822

Date Prepared: July 5, 2012

Trade Name of Device: iFuse Implant System®

Common or Usual Name: Orthopedic Rod

#### Classification Name:

21 C.F.R. 888.3040 – Smooth or threaded metallic bone fastener; Product Code OUR

Predicate Devices: SI Joint Fusion System by SI-BONE, Inc. (K080398, K092375 and K110838)

#### Intended Use

The iFuse System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

#### Device Description

The iFuse Implant System® consists of porous plasma spray coated titanium implants and associated surgical instruments. The iFuse Implant lengths range from 30mm to 70mm in 5mm increments with a diameter of 4.0 and 7.0 mm. The device is classified as smooth or threaded metallic bone fixation fasteners as Class II devices pursuant to 21 C.F.R. § 888.3040. The fusion rods are implanted using the same instrumentation previously described in K080398, K092375 and K110838.

1 ok2

### **Technological Characteristics**

The SI Fusion System consists of a series of metallic (titanium), porous plasma spray coated rods, intended for surgical implant within the bone to create fixation. The system includes 4.0 mm and 7.0 mm diameter fusion rods, which range in length from 30 mm to 70 mm.

### **Performance Data**

No performance testing was required to support the modified labeling that is the subject of the 510(k).

### **Substantial Equivalence**

The iFuse Implant System has the same intended use, indications for use, and technological characteristics as the predicate device. Thus, the iFuse Implant System is substantially equivalent to its predicate device.

### **Conclusions**

The iFuse Implant System is substantially equivalent to the predicate device.



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

SI-Bone, Incorporated  
% Domecus Consulting Services, LLC  
Ms. Cindy Domecus  
Principal  
3055 Olin Avenue, Suite 2200  
San Jose, California 95128

OCT 12 2012

Re: K122074

Trade/Device Name: iFuse Implant System

Regulation Number: 21 CFR 888.3040

Regulation Name: Smooth or threaded metallic bone fixation fastener

Regulatory Class: Class II

Product Code: OUR

Dated: July 9, 2012

Received: July 16, 2012

Dear Ms. Domecus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic,  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### **Indications for Use**

510(k) Number (if known):

Device Name: SI-BONE iFuse Implant System

Indications for Use:

The iFuse System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

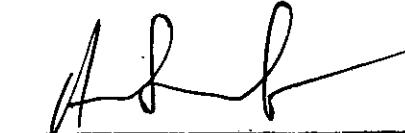
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

Page 1 of \_\_\_\_\_

510(k) Number K172074